

CLAIMS:

1. An intravaginal drug delivery device for administration into a vaginal environment, the device comprising at least one reservoir, the, or each, reservoir containing at least one pharmacologically active agent or a prodrug thereof, dispersed in a carrier system; and a sheath discontinuously surrounding the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment.
10. 2. An intravaginal drug delivery device according to Claim 1, in which the sheath defines one or more holes or openings, the, or each, hole or opening extending through the sheath to the at least one reservoir, so that at least part of the at least one reservoir is exposed, in use, to the vaginal environment.
15. 3. An intravaginal drug delivery device according to Claim 2, in which the, or each, hole or opening may extend to the surface of the at least one reservoir or may, in addition, extend at least partially into the at least one reservoir.
20. 4. An intravaginal drug delivery device according to Claim 2 or 3, in which the, or each, hole or opening may be of any shape or may be joined with an adjacent hole or opening to give a continuous opening in the form of a slit.
25. 5. An intravaginal drug delivery device according to Claim 2 or 3, in which the, or each, hole or opening is substantially cylindrical with a diameter in the range of about 0.5 to 6.5 mm, preferably about 1 to 5 mm.
30. 6. An intravaginal drug delivery device according to any one of Claims 2-5,

in which the, or each, hole or opening may extend through the sheath substantially normal to the reservoir surface.

7. An intravaginal drug delivery device according to any one of Claims 2-6, in which the device is substantially circular in transverse cross-section, and the, or each, hole extends substantially radially, inwardly or outwardly, through the sheath.

8. An intravaginal drug delivery device according to Claim 7, in which there are one to thirty, optionally two to ten, further optionally three to ten, of said holes, optionally aligned linearly, along the inner or outer circumference, optionally the inner circumference, of the intravaginal drug delivery device.

15. 9. An intravaginal drug delivery device according to any one of Claims 2-6, in which the device is a substantially cylindrical rod device, and said holes are provided at each terminal end of the rod.

10. An intravaginal drug delivery device according to Claim 9, in which the rod device defines a right circular cylinder and each base of the rod is partly or fully exposed, to define said holes.

20. 11. An intravaginal drug delivery device according to Claim 9 or 10, in which further holes or slits are provided extending substantially radially through the sheath.

25. 12. An intravaginal drug delivery device according to Claim 11, in which there are one to thirty, optionally two to ten, further optionally three to ten, of said further holes, optionally aligned linearly, along the circumference of the rod.

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13. An intravaginal drug delivery device according to any one of Claims 1-8, in which the device is a partial or complete toroid shape, preferably a partial or complete torus shape.
- 5 14. An intravaginal drug delivery device according to any one of the preceding claims, in which the reservoir additionally comprises at least one pore-forming excipient.
- 10 15. An intravaginal drug delivery device according to Claim 14, in which the pore-forming excipient comprises a water-soluble or water-swellable polysaccharide, preferably a cellulose derivative, more preferably hydroxyethylcellulose or croscarmellose; a monosaccharide or a disaccharide, preferably glucose or lactose; a water-soluble salt; a protein, preferably a gelatin; a nonionic surface active agent; a bile salt; an organic solvent, preferably ethoxydiglycol or polyethylene glycol; or a fatty acid ester, preferably containing 2 to 20 carbon atoms, more preferably a myristate ester.
- 15 16. An intravaginal drug delivery device according to any one of the preceding claims, in which the sheath additionally comprises at least one pharmacologically active agent.
- 20 17. A method of manufacturing an intravaginal drug delivery device according to any one of the preceding claims, said method comprising the steps of dispersing at least one pharmacologically active agent in a pharmaceutically acceptable carrier system; curing the reservoir; and applying a sheath to partly surround the reservoir.
- 25 18. A method of manufacturing an intravaginal drug delivery device according to any one of the claims 1 to 16, said method comprising injecting or extruding a reservoir material into a hollow sheath.